



# Agency Perspective on Electronic Regulatory Submission and Review

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# Topics

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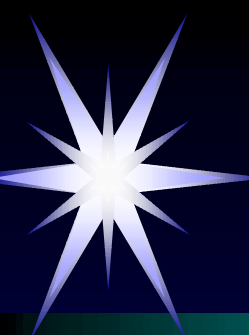
- Driving forces
- Overall goals
- Conceptual model for the ERSR program
- Progress of key components of ERSR
- Closing Points



# Driving Forces

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- Costs
- Legislation and regulations
- Electronic information experience
- International Harmonization



# Overall 2002 Electronic Goals

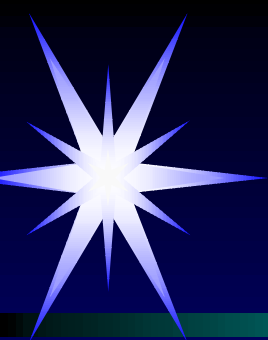
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- Receive and archive all electronic submissions
- Reviewers have desktop access to all electronic submissions, reviews, and references
- Tools and training for electronic review activities are available, and
- Publicly available information is on the internet

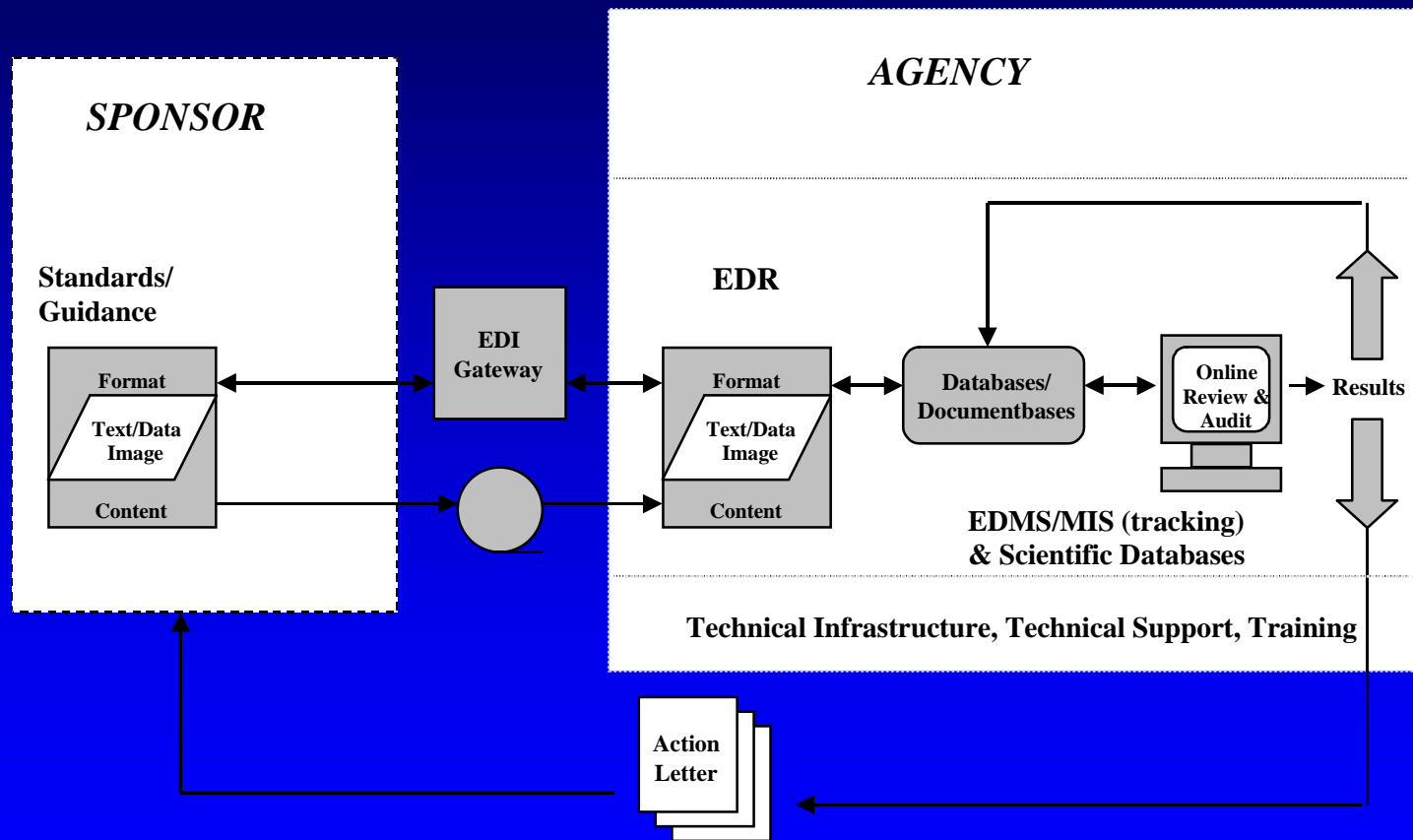


# To Meet These Goals...

- Established the Electronic Regulatory Submission and Review (ERSR) Program
  - conceptual model for a 'paperless' environment in 2002, and
  - 5 year IT plan
- Elevated this to a multi-center program
  - CDER, CBER, ORA, and Agency CIO Office



# ERSR Conceptual Model





# E-Submission Standards in Place

## ➤ Format

- prepared to accept in lieu of paper
  - PDF for text/image files, SAS Transport for clinical/statistical data
- adopted, but not acceptable in lieu of paper yet
  - SGML-tagged ASCII for adverse event reporting (ICH E2b)
- refer to Docket for the document types we now accept

## ➤ Content

- coordinating committees and ICH



# E-Submission Guidances in Place

- CDER/CBER General Considerations
  - format, media, processes
- CDER replacement of CRTs/CRFs with Full NDA
- Guidances for other document types?
  - CBER marketing applications guidance
  - CDER ANDAs, DMFs, INDs, advertising material, drug registration and listing, OTC Monographs...

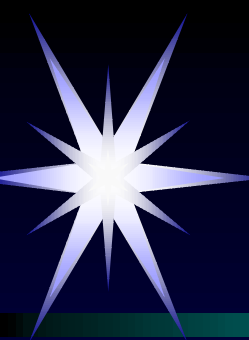




# Electronic Document Room (EDR)

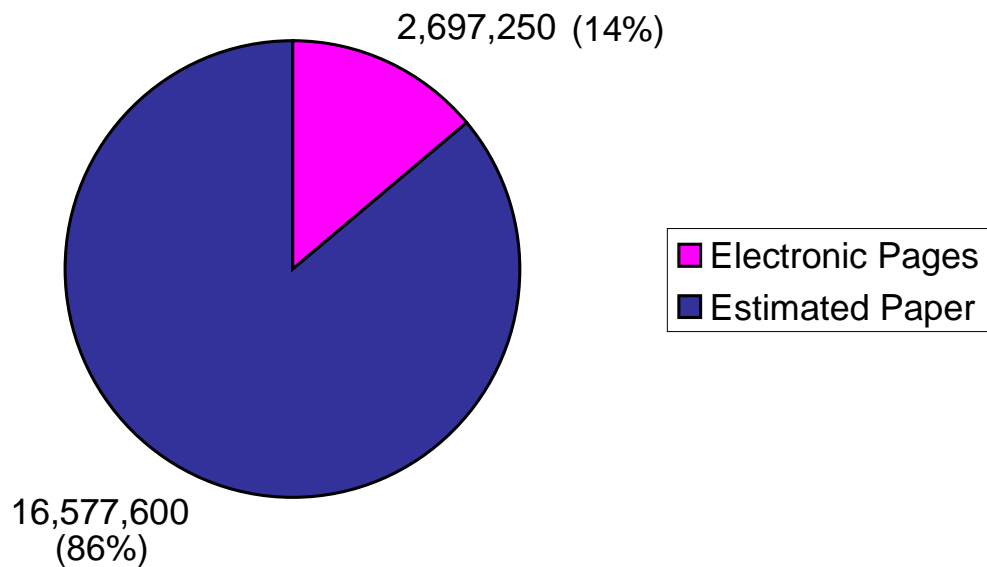
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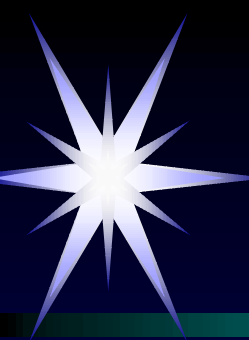
- Handles physical media only
  - MS-DOS formatted diskettes,
  - ISO 9660 CD-ROMS, and
  - DLT tape (Open VMS and NT 4.0)
- Inspects, loads, and stores the transport copy
  - creates two archive copies and a reviewer copy
- Offers the reviewer Web page access/searching



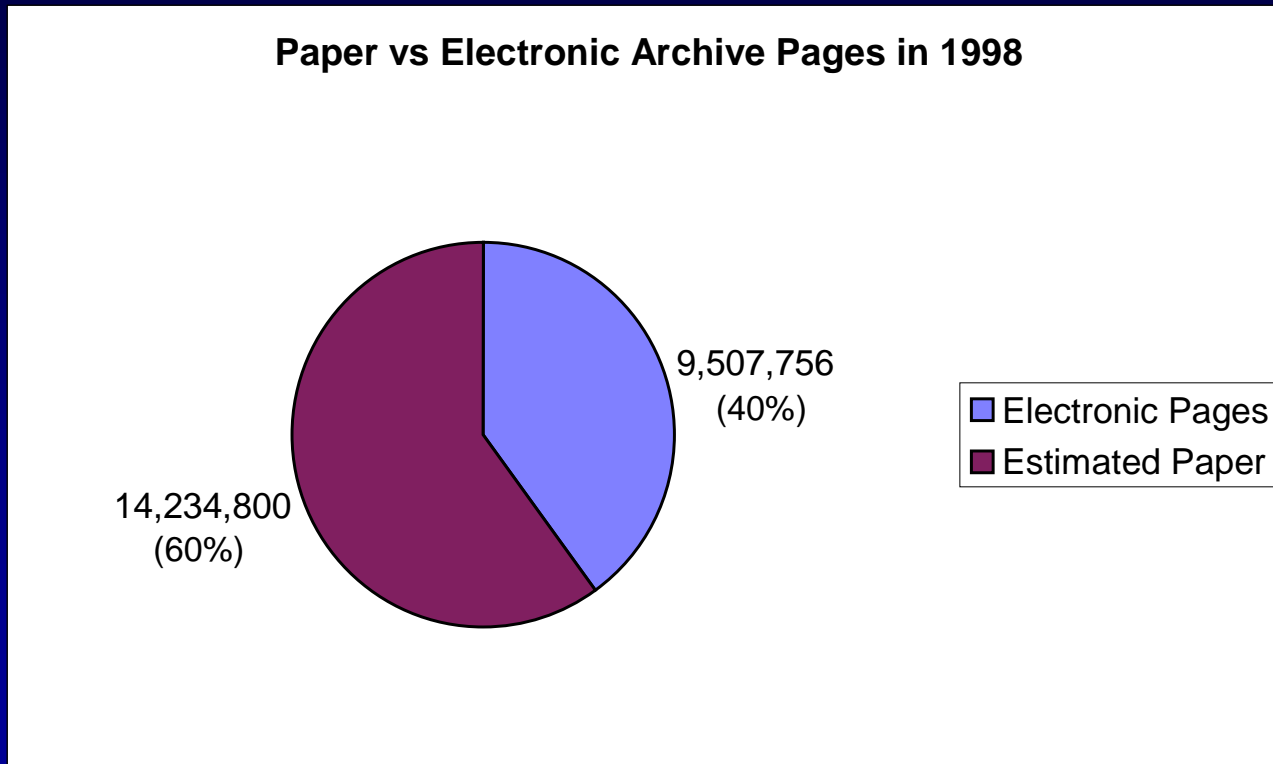
# Has EDR Saved Trees?

**Paper vs Electronic Archive Pages in 1997**





# Has EDR Saved Trees?





# Scientific Databases

- Standardizing and organizing data to improve processing and analysis
  - AERS
  - ANDA electronic review pilot program (EVA)
    - Bioequivalence data in generic drug applications
    - looking to move to new drugs, specifically CMC
  - Reference databases



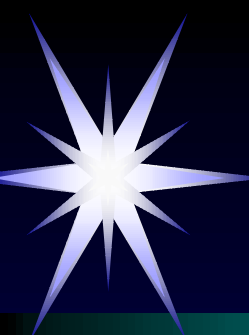
# Supporting Infrastructure

- EDR Training on a sample NDA, trained staff at buildings, and 1:1 when NDA arrives
- Division Files System (DFS)
  - an EDMS to manage, sign, and archive internally generated review documents
- Secure e-mail pilot with industry underway
  - builds off previous experiences: uses industry standards e.g. S/MIME, and supports server or client encryption



# Key Focus Areas in FY99

- Begin phase-out of the paper processes that parallel our EDMS and AERS
- Decide on electronic document query strategy
- Draft guidances for other document types
  - depends on infrastructure capacity e.g. EDR
- Implement a secure e-mail strategy
- Continue to harmonize across Centers



# Closing Points

- Standards and processes now in place works, and are making a big impact
- We are prepared to accept full electronic NDAs, including their amendments and supplements, in lieu of paper
- Secure e-mail communication with industry is on the horizon